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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/642,372

08/15/2003

Dusan Pavcnik

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COOK GROUP PATENT OFFICE

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EXAMINER

BLANCO, JAVIER G

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

01/07/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/642,372

Applicant(s)

PAVCNIK ET AL.

Examiner

JAVIER G. BLANCO

Art Unit

3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/18/2008; 9/18/2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is **non-final**.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 12-15, 19, 23-26, 30-35 and 37-39 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 12-15, 19, 23-26, 30-35 and 37-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 18, 2008 has been entered.

Response to Amendment

2. Applicants' amendment of claim 8 in the reply filed on October 18, 2008 is acknowledged.
3. Applicants' cancellation of claim 36 in the reply filed on October 18, 2008 is acknowledged.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claim 8 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of copending Application No. **10/828,716**. This was addressed in the previous office action.

Although the conflicting claims are not identical, they are not patentably distinct from each other because these applications claim a valve prosthesis comprising leaflets and a support frame/stent enclosed in (and supporting) said leaflets. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claim 8 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by **Dobben** (US 4,994,077 A).

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Referring to Figures 2, 3, 5, 6, 7A, 7B, 8, and 9, Dobben discloses a valve prosthesis comprising:

- a.** A support frame (**Figures 2-3:** support frame 40; **Figures 7-9:** support frame 94 and/or stent) supporting two or more leaflets (**Figures 2-3:** 42, 44; **Figures 7-9:** 90, 92), the two or more leaflets including a co-aptation position and cooperatively forming a valve orifice (**first interpretation:** when valve/flap is open; **second interpretation:** space or orifice formed between the disks/discs), at least a portion of the support frame supporting each of the two or more leaflets at a point adjacent the valve orifice; each of the two or more leaflets including opposing proximal and distal leaflet surfaces and first and second outer edges (e.g., peripheral edges); the support frame comprising frame elements (**Figures 2-3:** 48, 50; **Figures 7-9:** side elements of 94 and/or bends 96, 98) around which the first and second outer edges of the two or more leaflets are wrapped (e.g., Figure 3: wrapping around or by 47; Figures 8 and 9: wrapping around 96, 98) *to allow* the first and second outer edges of each of the two or more leaflets to non-circumferentially engage a wall of the vascular vessel such that the frame elements are non-centering of the co-aptation position within the vascular vessel; and
- b.** At least one centering support element (**Figures 2-3:** strut/arm 24; **Figures 7-9:** entire stent **and/or** struts/arms 84, 86), each of the at least one centering support element attached to the frame elements only at one or more points adjacent the two or more leaflets and including a portion that traverses one of the two or more leaflets from the first outer edge to the second outer edge and is free of contact with the proximal leaflet surface and the distal leaflet surface of one of the two or more leaflets.

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8. Claim 8 is rejected under 35 U.S.C. 102(e) as being clearly anticipated by **Shaolian et al.** (US 6,299,637 B1).

Referring to Figures 5-10, Shaolian et al. disclose a valve prosthesis (see column 9, line 29 to column 10, line 10) comprising:

- a.** A support frame (leaflet frame 72 **and/or** connector/loop 68, 70) supporting two or more leaflets (leaflets 76, 78; leaflets 90, 92), the two or more leaflets including a co-aptation position (see coaptive leading edges 73) and cooperatively forming a valve orifice (**first interpretation:** when leaflets are in the open position; **second interpretation:** space or orifice formed between by each leaflet pocket), at least a portion of the support frame supporting each of the two or more leaflets at a point adjacent the valve orifice; each of the two or more leaflets including opposing proximal and distal leaflet surfaces and first and second outer edges (e.g., peripheral edges); the support frame comprising frame elements (e.g., struts, side elements, connector/loop) around which the first and second outer edges of the two or more leaflets are wrapped *to allow* the first and second outer edges of each of the two or more leaflets to non- circumferentially engage a wall of the vascular vessel such that the frame elements are non-centering of the co-aptation position within the vascular vessel; and
- b.** At least one centering support element (wire frame 44 and/or hinge loops 60, 62), each of the at least one centering support element attached to the frame elements only at one or more points adjacent the two or more leaflets and including a portion that traverses one of the two or more leaflets from the first outer edge to the second outer edge and is free of contact with the proximal leaflet surface and the distal leaflet surface of one of the two or more leaflets.

9. Claim 8 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by **Moll et al.** (US 6,287,334 B1).

Referring to Figures 1, 2, 5, and 6, Moll et al. disclose a valve prosthesis (1) comprising:

- a. A support frame (10) supporting two or more leaflets (6), the two or more leaflets including a co-aptation position (see Figures 1, 5, and 6) and cooperatively forming a valve orifice (see Figures 1, 5, and 6), at least a portion of the support frame supporting each of the two or more leaflets at a point adjacent the valve orifice; each of the two or more leaflets including opposing proximal and distal leaflet surfaces and first and second outer edges (e.g., peripheral edges); the support frame comprising frame elements (non-circumferential elements 8) around which the first and second outer edges of the two or more leaflets are wrapped (clearly shown in Figure 1) *to allow* the first and second outer edges of each of the two or more leaflets to non-circumferentially engage a wall of the vascular vessel such that the frame elements are non-centering of the co-aptation position within the vascular vessel; and
- b. At least one centering support element (Figures 1 and 2: a circumferential element on distal end 4, or all of said circumferential elements as an unit), each of the at least one centering support element attached to the frame elements only at one or more points adjacent the two or more leaflets and including a portion that traverses one of the two or more leaflets from the first outer edge to the second outer edge and is free of contact with the proximal leaflet surface and the distal leaflet surface of one of the two or more leaflets.

In an alternative interpretation, the opposing “proximal surface” and “distal surface” of each of the two or more leaflets are broadly interpreted to be any proximal surface and any distal surface of wall 12. None of said surfaces is in contact with any of the struts/elements of support

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frame 10. Therefore any (or all of) the circumferential elements on proximal end 2 can also be broadly interpreted as the "at least one centering support element ".

Response to Arguments

10. Applicant's arguments with respect to claim 8 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:00 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571)272-4749. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Javier G. Blanco/

Examiner, Art Unit 3774

/David H Willse/

Primary Examiner, Art Unit 3738